

REMARKS

Claims 1-9 stand rejected under 35 USC 103(a) as being unpatentable over Krimm et al (US 2,784,182) in view of Schirmann et al (US 3,819,653). Claims 1-7 stand rejected under 35 USC 103(a) as being unpatentable over Bulachkova et al (abstract only of Russian paper) in view of Schirmann et al.

Applicants have traversed the rejection for lack of **prima facie obviousness** in that the record does not provide a basis for the Examiner's proposed modification, with a reasonable expectation of success. More specifically, the record does not provide a **basis proposed modification of adding water to water-miscible solvents in the claimed process.**

Seemingly, the Examiner in the final office action seems to be arguing that the burden is met by the overruled holding of "Winslow Tableau" (In re Winslow, 151 USPQ 48 CCPA 1966) wherein the skilled artisan is presumed to be aware of the all pertinent art.

Based on the premise of the Winslow Tableau, the Examiner argues against Applicants' arguments relating lack of **prima facie obviousness** as follows:

"This assessment is speculation on applicant's behalf because one of ordinary skill in the art deemed to be aware of all the pertinent art in the field."

Applicants submit that the Examiner characterization of Applicants' argument of lack of **prima facie obviousness**, and the apparent requirement of proof in support of such argument is against the weight of authority in the patent laws. It is well established that the Examiner must point to factual basis in the references or the general knowledge in the art. It is insufficient to state that the one skilled in the art would be aware of such basis, without any support therefor.

Seemingly based on this premise, the Examiner concludes without factual support that the claims fall within the generic process of the prior art, that the prior art

teaches "several combinations" which would lead to the claims, and that the prior art can be optimized to the claims.

These unsupported conclusions are discussed more fully hereunder. At page 3, last paragraph through page 4, line 2 of the Office Action, the Examiner argues without factual support that:

"The prior art teach generic process of preparing oxaziridines using analogous reagents such as aldehydes (column 2, line 67 of US '182), mono-analogous reagents such as aldehydes (column 2, line 67 of US '182), mono-peroxy phthalic acid (column 3, line 38 of US '182), water-miscible solvent e.g. chlorobenzene (col. 3, line 69 of US '182), at an overlapping temperature range. The differences between the instant claims and the prior art are so negligible, that one of ordinary skill in the chemical art would expect slight variations to be within the expected purview of 35 U.S.C. 103(a)." (Delineation is Applicants for emphasis).

Statements such as the reagents are analogous and that the differences are negligible are mere conclusions, which are not based on facts. Applicants hasten to note that the Examiner has not ascertained the negligible differences between the prior art and the claims.

For the purpose of further prosecution or Appeal, Applicants hereby request that the Examiner ascertains the negligible differences between the prior art and the claims.

Applicants, for their part, have stated that the claims differ from the prior art in at least one respect in failing to teach or suggest the addition of water to water-miscible solvents. Applicants have shown why the skilled artisan would not have added water to water-miscible solvents, in the preparation of the referenced compounds, let alone the claimed compounds. Applicants' position remains undisputed by facts of record.

Should the Examiner continue to rely on general knowledge, Applicants for the purpose of further prosecution or Appeal, request that the Examiner provide data supporting the assertion that such an addition is within the general knowledge of the skilled artisan, In re Lee, 61 USPQ 1430 61 USPQ2d 1430 (CAFC 2000).

At page 4, lines 2-6 of the Office Action, the Examiner argues for the combination of the references without factual support for making the proposed combinations. Specifically the Examiner argues that:

"The disclosure of Krimm et al and further in view of Schirmann et al or Bulachkova et al teach several combinations that would easily place Applicants' invention in possession of the public at the time of Applicants' invention was filed. The motivation to make the claimed process derives from the expectation that the use of analogous reagents under specific set of reaction conditions would have made similar products." (Delineation is applicants)

At page 4, lines 6-10, the Examiner reiterated his arguments about optimization without any factual support by stating that:

"The determination of optimum reaction conditions is routine experimentation and to one skilled in the art. Changes in temperature, concentration of reactants, or both are not patentable modification in the absence of unexpected results, which is different in kind and not degree (In re Boesch 205 USPQ, 215 CCPA 1980)"

Finally, at page 4, lines 10-13, the Examiner states without factual support that there are exemplary teachings of the process in the art. Specifically, the Examiner states that:

"Since there is an exemplary teaching of a process to obtain the claimed compounds in the prior art, one would have reasonable expectation that such modification and optimization of reaction conditions would give compounds with similar rate of recovery."

The Examiner has not identified an example of the claimed process in the cited references.

From the foregoing, it is quite clear that the Examiner has not advanced factual support for his conclusion of obviousness. Hence, there remains the issue of whether the Examiner has indeed established a *prima facie* case of obviousness based on the cited references.

It is well settled in the law that to establish *prima facie* case obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in

the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

It is also well settled in the law that the teaching to make the claimed combination and the reasonable expectation of success must both be found the prior art and not based on applicant's disclosure. In re Vaeck 20 USPQ2d 1438 (Fed. Cir. 1991).

The initial burden is on the Examiner to provide some suggestion of desirability of doing what the inventor has done. The references must explicitly or implicitly suggest the claimed invention, or the Examiner must present a convincing line of reasoning as to why the skilled artisan would have found the claimed invention to be obvious.

In this case, the record does not point to how the skilled artisan having the references before him would have modified the prior art to the claims. The mere fact that the references can be combined or modified does not render the proposed combination obvious unless the prior art suggests the desirability of making the combination as discussed above. The mere fact that the references fall within the broad class of the prior art does not render the claims obvious, absent some basis in the art for making the proposed modification. Other than the unsupported assertion of general knowledge, the Examiner has not pointed to evidence or practical reason supporting his proposed modification.

Where the Examiner has not established a *prima facie* case, Applicants do not need to submit any evidence of nonobviousness in rebuttal.

Nonetheless, Applicants in their previous response to the office action provided ample reasons supporting their assertion that the Examiner has failed to make a *prima facie* case of obviousness. Applicants' arguments are stated hereunder.

The Examiner's proposed combination of references does not lead to the claims encompassing a mixture of water and a water-miscible solvent. For, adding more water to the process of Krimm et al would have led to an unsatisfactory combination of water and water-miscible organic solvent. Where the proposed modification would be unsatisfactory, it cannot be said to render the claims obvious, In re Gordon 221 USPQ 1125 (Fed Cir. 1984). For, it is well known that the presence of water is detrimental for the reaction of imines with per-compounds. In the presence of acids and water, the imines used as starting materials tend to hydrolyze, thereby lowering the yield achieved. Additionally, the presence of water and acid results in a hydrolytic cleavage of the oxaziridines formed into corresponding aldehyde and the corresponding NO-substituted hydroxylamine. The latter is easily oxidized to give an undesired nitroso-compound as by-product. These side-reactions additionally lower the yield (see the captioned application, at page 2, lines 12-15 and lines 17-23). These undesired consequences relating to the presence of water are reflected by the poor yields achieved in the Krimm process.

Applicants further traverse the rejection based on the assertion that the addition of water constitutes optimization. It is well established that a particular parameter must first be recognized as result-effective, i.e., a variable which achieves a recognized result before the determination of the optimum or workable range of said variable, In re Antonie 195 USPQ 6 (CCPA 1997). In this case, the record does not show that the addition of water was recognized as a result-effective variable. Therefore, a basis for arguing optimization has not been established. In view of the foregoing, Applicants submit that Krimm in view of Schirmann does not support a case of *prima facie* obviousness.

Quite instructive is the teaching of Bulachkova, which relates to preparation of oxaziridines by reacting imines with perbenzoic acid, wherein the reaction is carried out as a phase transfer epoxidation. This means that the reaction system comprises water and a non-water miscible organic solvent, as well as a phase-transfer catalyst. The Examiner has not stated how the combination of water and non-water miscible organic solvent teaches or suggests the claims.

To be sure, two-phase systems without a phase transfer-catalyst are known in the preparation of oxaziridines, as acknowledged by the citation of WO-A-00/02848 at page 2, line 25ff of the captioned application. However process employing these systems are disadvantaged, if up scaling of the reaction is intended.

The record is devoid of a basis in Schirmann for modifying Bulachkova in order to overcome its disadvantages such as those associated with scaling up the reaction. Therefore Bulachkova, in view of Schirmann, fails to support a case for *prima facie* obviousness.

Finally, Applicants submit that the Examiner ignored or dismissed as optimization the marked improvements that attend the process. The combination of water with water-miscible solvent results in the observed high yields of the desired oxaziridines. Additionally the addition of a base during the reaction – and not afterwards - results in further improvement of the yield, by reducing the acidic side reactions described above. Also, the presence of water according to the present invention makes the handling of the percarboxylic acid safer.

The Examiner has failed to show that combination of water with water-miscible solvents would results in improvement in yield of oxaziridines. The Examiner has failed to show that the order of addition of a based would result in improvement in yield.

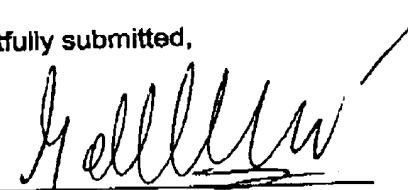
In view of the foregoing which rebut technical reasons for the proposed modification, it is untenable to suggest that the proposed modifications would have led to the claims. It is untenable to suggest the addition of water to Krimm et al process where the proposed modification as shown above would be unsatisfactory. It is untenable to suggest that Shirmann's teaching of preparing oxaziridines by reacting imine with hydrogen peroxide in the presence of nitrile suggest the addition of water. Such a suggestion would be impermissibly based on picking and choosing the ingredients of the prior art in light of Applicants' disclosure. Finally it would be untenable to

suggest that Bulachkova et al's teaching of a reaction system comprising water and a non-water miscible organic solvent, as well as a phase-transfer catalyst would have suggested the use of water in combination with water-miscible solvent.

With respect to this identified difference, it is clear that the Examiner has not established factual support for the conclusion of obviousness. Therefore, Applicant prays for the withdrawal of the rejection and allowance of the claims.

In the alternative, and for the purpose of appeal, Applicants request an explicit statement of the differences between the prior art and the claims, and data in support of the assertion that the differences would have been within the general knowledge of the skilled artisan.

Respectfully submitted,

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